

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 1:22-cv-441

ABBOTT LABORATORIES, a corporation  
doing business as ABBOTT NUTRITION,  
and KEENAN S. GALE, TJ HATHAWAY,  
and LORI J. RANDALL, individuals,

Hon. Hala Y. Jarbou

Defendants.

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**EXPEDITED CONSIDERATION REQUESTED**

JOINT AGREED MOTION TO AMEND CONSENT DECREE

The United States of America and Defendants respectfully move to Amend the Consent Decree of Permanent Injunction entered on May 16, 2022 (the “Decree,” ECF No. 8), and in support thereof state as follows:

1. The Decree defines “Inventory Products” to “refer only to the non-recalled powdered finished products manufactured at the Sturgis Facility and in Defendants’ possession, custody, or control as of March 18, 2022, the close of FDA’s inspection at Defendants’ facilities located at 901 North Centerville Road, Sturgis, Michigan 490901.” Decree ¶ 7(E) (ECF No. 8, PageID.64).

2. The Decree also defines “Specialty Operations” as “Defendants’ manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is: (1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or (2) Any powdered product for non-infants (older than 12 months of age) that serves similar

nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1).” Decree ¶ 7(G) (ECF No. 8, PageID.64-65).

3. The Parties respectfully request that Paragraph 7(G) of the Decree be amended and modified to include the following clarifying definition of “Specialty Operations”:

“Specialty Operations” shall refer to Defendants’ manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1),

*except that such food shall not include Inventory Products defined in paragraph 7(E).*

4. WHEREFORE, the Parties respectfully request that the Court grant the relief requested above.

5. The Parties also respectfully request the Court’s expedited review of this Joint Motion due to the ongoing nationwide infant formula shortage.

Respectfully and jointed submitted:

MARK A. TOTTEN  
United States Attorney

*s/ Andrew J. Hull*

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*Counsel for Plaintiff*

Dated: May 21, 2022

*s/ Mark E. Schneider (with permission)*

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Dated: May 21, 2022